JUN - 7 2004

Exhibit IV: 510(k) Summary

K041385

Schick Computed Oral Radiology System

Common/Classification Name: Solid State X-ray Imager
21 CFR892.1650

Schick Technologies, Inc.
30-00 47th Avenue
Long Island City, NY 11101
718-937-5765, 718-937-5962 (FAX)
Contact: Daniel Michaeli, Prepared: May 24, 2004

A. Legally Marketed Predicate Devices

The original Computed Oral Radiology System notification was cleared on January 31st, 1994 (K933455). The device and its predicate are small digital imaging receptors that may be used in place of dental x-ray film.

B. Modification Description

The new control mechanism differs from the predicate in that image acquisition may additionally be triggered through a hardwire to an x-ray tube. This modification allows for a quicker x-ray response time and may improve ergonomics as it eliminates the need for a standalone remote module.

The existing firmware has been altered to support the modified and additional hardware. The new remote module may be housed within a specified x-ray source. The modification in no way effects the fundamental technology governing image acquisition.

C. Indications for Use

The Computed Oral Radiology System is indicated for patients undergoing an intra-oral dental x-ray examination. It produces instant, digital, intra-oral x-ray images of a patient's mouth while reducing the necessary x-ray dosage. This device modification in no way alters the indications for use of this machine beyond what was originally cleared in K933455.

D. Substantial Equivalence Summary

A risk analysis established the areas of concern. The principal risk is unintended x-ray exposure. These areas have been evaluated following bench, and third-party safety testing. All validation activities have demonstrated that the

predetermined acceptance criteria were met. Where appropriate, warnings have been incorporated within the user manual.

E. Conclusions

Schick Technologies has demonstrated through a risk analysis and validation studies that the device modification is substantially equivalent to the already cleared and marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Daniel Michaeli
Director of Science Development
Schick Technologies, Inc.
30-30 47th Avenue
LONG ISLAND CITY NY 11101

AUG 23 2013

Re: K041385
Trade/Device Name: Computed Oral Radiology System
Regulation Number: 21 CFR 892.1810
Regulation Name: Intraoral source x-ray system
Regulatory Class: II
Product Code: EAP and MQB
Dated: May 24, 2004
Received: May 25, 2004

Dear Mr. Michaeli:

This letter corrects our substantially equivalent letter of June 7, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041385

Device Name: Computed Oral Radiology System

Indications For Use:

The Computed Oral Radiology System is indicated for patients undergoing an intra-oral dental x-ray examination. It produces instant, digital, intra-oral x-ray images of a patient's mouth while reducing the necessary x-ray dosage.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041385